

Remarks

Claims 1-10 and 13-27 are pending. Claim 5 was previously withdrawn under an election requirement. Claims 11-12 were previously cancelled. Claims 21-23 are objected to. For the reasons set forth below, the grounds of rejection are respectfully traversed.

With regard to the Examiner's observation concerning the use of "proximal end" rather than "rearward end" in claims 21-23, applicant agrees that consistent terminology would be preferable. However, in drafting claims 21-23, applicant concluded that in view of the existing structure of the claims, it would be preferable to use "proximal end" in order to avoid possible confusion with references to the "rearward end" of the elongate body. Additionally, because the term "distal" was originally used to describe the location of the fins, it appeared appropriate to use "proximate" to describe the proximal/rearward end of the fins.

Applicant appreciates the indication that Claims 21-23 would be allowable if rewritten in independent form. Applicant has elected to pursue further review of the pending claims, and requests reconsideration.

Applicant notes its comments concerning Meyer are being misinterpreted. Applicant did not take the position that Meyer is a "cementless" implant. Applicant pointed out that one of the primary objectives of Meyer is to overcome problems with prior art cemented hip implants, and that the cited references provide no suggestion or motivation to modify the centralizer of Mackwood Ling to meet the requirements of the claimed invention. Meyers mentions that in order to avoid having to provide a plurality of different sized reamers to match different sizes of implant, PMMA cement can be used to fix the distal portion of the stem in the canal of the femur. (Meyers col. 5, lines 60-end; col. 6, lines 60-64; Fig. 4). Based on Meyer's reference to cementing the distal portion of the stem, the Examiner concludes that "Thus, the centralizer plug of Mackwood Ling would be useful in stabilizing the cemented distal stem of the prosthesis." As previously noted by applicant, centralizers are designed for and have long been used for this purpose. It is therefore not clear to applicant why this well known function of centralizers would suggest modifying the centralizer in the manner necessary to meet the limitations of the claimed invention. Applicant also questions whether a centralizer would be useful with the Meyer implant. First, as shown in Meyer Figure 4, the proximal end the Meyer implant is designed to fit snugly against the surrounding bone. The location of the distal part of the Meyer stem is determined by the tight fit between the proximal stem and the surrounding bone. In view of this

configuration, a centralizer on the distal end of the implant would not serve to centralize the implant. Second, based on Meyer Figure 4, a surgeon would have a difficult time passing the centralizer through the narrow proximal portion of the patient's intramedullary canal and into the wider distal portion. To do so, the centralizer would have to be pliable in order to pass through the narrow portion, and it would have to be inserted separately from the stem. However, the question is not whether a centralizer would be useful in stabilizing the cemented distal stem of the prosthesis. The question is whether the cited references provide a suggestion to significantly change the structure of the Mackwood Ling centralizer such that it is positioned on the distal end of a compacting broach for use in preparing a femoral canal for receipt of an implant. For the reasons stated in applicant's previous responses, it is respectfully submitted that in the absence of applicant's disclosure, there is simply no teaching, suggestion or motivation to do so.

With regard to applicant's position that combining the cited references would destroy the function of the Mackwood Ling centralizer, the Examiner notes that in Meyer, the femoral canal is prepared first for the stem, and that the self rasping portion of the prosthesis is only located near the upper region. The Examiner takes the position that using the centralizer plug of Mackwood Ling with the Meyer reference would not destroy their intended functions, since the rasping-portion of the implant is only necessary to provide a tight fit at the upper regions of the prosthesis. The Examiner concludes that the "centralizer would not be involved in the broaching procedure, since the femoral canal adjacent the stem portion will have already been reamed/broached, and only the self-rasping portion of the prosthesis of Meyer broaches the upper portion of the canal." The Examiner's observation appears to confirm applicant's point. Since the centralizer will not be involved in the broaching procedure, why would a person of skill in the art at the time of the invention have been motivated to provide a broach with a plurality of fins on the distal end? As previously noted, significant modifications would have to be made to the Mackwood Ling centralizer (as well as to the Meyer), and the intended function of the prior art devices would be destroyed. For example, if the Mackwood Ling centralizer were placed on the Meyer implant during broaching, the centralizer would dislodge during the broaching process. Independent claims 1 and 2 further specify "said fins being disposed inwardly of said cutting teeth." This feature is not found in the cited references, and modifying Mackwood Ling to meet this requirement would also destroy the function of Mackwood Ling. Applicant's inwardly disposed fins serve to orient the broach during the broaching process, but without affecting the

path of the teeth of the broach as the teeth broach the surrounding bone. In contrast, as can be seen in Mackwood Ling Figure 3, a centralizer is specifically designed to jut out from the distal end of the implant, such that the periphery of the centralizer abuts against the surrounding bone. If the Mackwood Ling centralizer were reconfigured such that the centralizer were disposed inwardly of the cutting components of the Meyer stem, the function of the centralizer would be destroyed, because the centralizer would not abut the surrounding bone. (Compare Meyer Figure 4 with Mackwood Ling Figure 3; see also Applicant's Figure 1).

With regard to Applicant's assertion that the Meyer reference does not show a prosthetic component with a rectangular cross section in claim 3, the Examiner notes that the prosthetic component is recited functionally, i.e. "to receive a prosthetic component of rectangular cross-section." The Examiner concludes that in view of the functional recitation, the device of "Meyer need only possess corner edges that are capable of matching corners of a prosthetic component with rectangular cross section." It is difficult to see how Meyer's plurality of broach fins 28 radially disposed on a prosthetic having a round cross-section could be interpreted as "four corner edges matched to corresponding corners of a prosthetic component of rectangular cross-section." As applicant previously noted, applicant's specification should serve as the guide for interpreting the meaning of the claim phrase "a prosthetic component of rectangular cross section." As discussed at ¶0027 of applicant's published application, Figure 8 shows how applicant's claimed compacting broach 10 forms a centered cavity 58 in the intramedullary canal 52 for close receipt of side walls 60 of the final rectangular stem implant 26 (side walls 60 and stem 26 are indicated but not shown in Figure 8). It is respectfully suggested that interpreting Meyer as teaching the claimed configuration disregards applicant's description of the respective terms.

With reference to claims 24-27, nothing in the cited references teaches or suggests a plurality of fins fixedly attached to a distal end of the elongate body of a compactor instrument. Mackwood Ling's centralizer plug merely slips over the distal end of the final implant. Applicant's specification provides the sole suggestion for the claimed configuration.

Applicant maintains its position that applicant's disclosure is being used to reconstruct the claimed invention. In reply to applicant's arguments concerning hindsight reconstruction, the Examiner notes that so long as the obviousness showing takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and

does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper, citing *In re McLaughlin*, 443 F.2d 1392,170 USPQ 209 (CCPA 1971). However, the problem with the obviousness showing is that it based solely on knowledge gleaned from applicant's disclosure. The only showing of obviousness appears in the following paragraph of the office action:

It would have been obvious to one of ordinary skill in the art to construct the device of Meyer with a bullet-shaped distal tip comprising three fins and four fins fixedly attached, spaced at 90 degrees spaced locations about the central longitudinal axis, extending radial to the central longitudinal axis and extending longitudinally, distally from the forward end of the body to converge at an apex aligned with the central longitudinal axis, the fins being disposed inwardly in view of Mackwood Ling et al. in order to centralize the device at the distal end.

(Final Office Action, pp. 3-4). It is respectfully suggested that the foregoing merely states a conclusion, and is not sufficient to meet the Commissioner's burden of establishing a *prima facie* showing of obviousness.

Applicant's previous arguments are reiterated and incorporated herein by reference. Reconsideration is respectfully requested.

It is believed that this response has been filed within the applicable time period for responding and that no extension of time is therefore required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no fees are due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,

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